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Conceptualising Colour-Changing Expiry Labels for Medication Safety in Pharmaceutical Packaging

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Abstract

Introduction: Expired medicines pose significant risks to patient safety and contribute to pharmaceutical waste. In most pharmacy settings, expiry monitoring remains manual, which is time-consuming and prone to error. This paper presents a novel conceptual framework for smart colour-changing labels that visually indicate remaining shelf life through green, yellow, and red stages. The proposed system integrates principles of pharmaceutical technology, materials science, and chemical kinetics to support proactive medication safety and inventory management. Potential mechanisms include structural-coloured polymers and controlled-release microcapsules, with mathematical modelling linking label colour transitions to expected drug potency over time. While no prototype has yet been developed, this work establishes a theoretical foundation for future experimental validation, feasibility assessment, and integration into pharmaceutical packaging workflows. The proposed approach has the potential to enhance expiry tracking, reduce medication errors, optimise stock rotation, and improve confidence in pharmaceutical quality and safety.

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Introduction

Medicines have expiration dates to help ensure that they remain safe and effective. When a drug passes its expiry date, it may lose its strength or become chemically unstable. Taking expired medications can reduce treatment effectiveness, delay recovery, or even lead to harmful side effects (Braund, Peake, & Shieffelbien, 2009). Unfortunately, the problem of expired medicines is common in both hospital and community pharmacy settings. A study by the World Health Organization (WHO) highlights that expired medicines are a major contributor to pharmaceutical waste worldwide, especially when there is no proper system to manage expiry tracking (World Health Organization Regional Office for the Eastern Mediterranean, 2006).

In most pharmacies today, expiry monitoring is still done manually. Pharmacists and pharmacy technicians often have to check each item one by one to find near-expired or expired stock. This process is slow, prone to human error, and time-consuming, especially in busy community pharmacies where hundreds of different medications are stored (Friday & Sorlihu, 2025), (Jaju, Varshney, Gupta, Bihani, & Karim, 2023). Mistakes can happen when dates are misread or missed, leading to potential patient safety issues and financial losses due to wastage.

Pharmacists play a critical role in ensuring the safe and appropriate use of medicines, particularly in the management of chronic conditions, and proper medication management is essential to avoid complications (Taghizadeh, 2025). In such cases, the administration of an expired or sub-potent medicine could result in poor disease control, highlighting the need for better systems to detect and remove expired medications before they are dispensed.

To address this, some pharmacies use digital inventory management systems that send alerts when medicines are about to expire (Friday & Sorlihu, 2025). While helpful, these systems are often expensive, not widely adopted in low-resource settings, and still require human involvement to remove or relabel stock (Berger et al., 2007). Additionally, these systems do not always provide a clear visual signal that a medicine is nearing expiration. In real-world practice, especially during high workload periods, visual cues can be much more effective than digital alerts alone.

There is growing research on smart packaging technologies across multiple industries. In the food sector, freshness indicators using colorimetric changes have been developed to detect spoilage based on pH shifts, time, or gases emitted during microbial growth (Lee & Shin, 2019). Similarly, in vaccine cold chains, temperature-sensitive labels are used to show if a product has been exposed to unsafe conditions (Zaffran, 1996). In the pharmaceutical context, most smart sensor technologies proposed to date focus on temperature monitoring rather than expiration tracking over time (Mahajan, Caleb, Singh, Watkins, & Geyer, 2014).

Some early-stage design projects have explored the use of colour-changing labels for pharmaceuticals. For instance, an engineering team proposed a prototype using a hydrogel-pH dye combination that gradually shifts colour as a function of time and chemical reaction (Sharabarin, Finstad, Rakos, & Arellano, 2021). However, these efforts remain at the proof-of-concept level and have not yet been evaluated within pharmacy workflows or adapted to common oral dosage forms stored at room temperature. Moreover, existing approaches typically rely on chemical diffusion, whereas this paper proposes alternative methods using structural-coloured polymers or controlled-release microcapsule techniques with greater design flexibility and stability.

In other industries such as food packaging and vaccine distribution, smart labelling technologies have been successfully used to improve safety and reduce spoilage. For example, Time-Temperature Indicators (TTIs) are small stickers that change colour when a food item or vaccine has been exposed to high temperatures for too long (Kuswandi et al., 2011). These indicators are now widely used in cold chain monitoring for temperature-sensitive products. In the food industry, colour-changing freshness labels have been developed to detect spoilage by sensing gases or pH changes produced by microbial growth (Lee, Lim, Lee, & Shin, 2024). These systems provide a visual, low-cost solution that staff or consumers can understand at a glance.

Despite these advances in smart labelling, there is very little research or implementation of similar technologies in pharmacy practice, especially for time-based expiry indication. Most pharmaceutical labelling still depends on printed expiration dates, which are small, hard to read, and static. Few efforts have been made to use calorimetric technology for medicines that are stored at room temperature, such as tablets and capsules.

To date, there is no documented or commercially available system in pharmacy settings that uses time-based visual indicators to signal medicine expiry. This research gap presents a clear opportunity for innovation in pharmaceutical labelling, particularly for improving safety, efficiency, and patient trust.

Given these challenges, this paper presents a new idea: a colour-changing expiry label that visually shows how close a medicine is to expiring. The goal is to help pharmacists, technicians, and even patients quickly identify medicines that are still safe to use, those nearing expiry, and those that should be discarded. This concept builds on existing materials science technologies and proposes an easy-to-use, low-cost addition to pharmacy safety and inventory systems. If successfully developed, this innovation could help reduce medication errors, improve stock rotation practices, and reduce pharmaceutical waste especially in settings where access to digital systems is limited.

Unlike existing time–temperature indicators used in food or vaccine packaging the novelty of this work lies in the integration of predictive pharmaceutical stability kinetics with pre-calibrated smart labels designed specifically for room-temperature solid dosage forms. By linking first-order degradation models and stability thresholds directly to time-based visual signals, this concept provides a quantitative and pharmaceutically grounded framework for expiry indication rather than a purely reactive or environmental sensor.

Accordingly, this concept paper is guided by three main questions: (1) how can a gradual colour change be aligned with known drug stability data over time; (2) which types of smart materials may be suitable for indicating expiry in room-temperature oral dosage forms; and (3) how could such labels be realistically used within pharmacy workflows to support FEFO stock rotation and medication safety. Rather than presenting experimental results, this paper provides a conceptual framework to guide future material development and applied research.

Design Concept and Theoretical Basis

Concept Proposal

How the label would work

Colour coding is a recognized and effective tool to improve patient safety and reduce medication errors (Janik & Vender, 2019). The proposed smart expiry label would display three progressive colour stages that evolve continuously over time rather than changing abruptly:

- Green: Safe to use (more than 3 months remaining before expiry)
- Yellow: Warning stage (1 to 3 months remaining)
- Red: Near-expiry or expired (less than 1 week remaining)

The gradual transition between these colours provides an intuitive visual timeline of remaining shelf life. Importantly, the label is not intended to directly measure drug concentration, but rather to act as a time-responsive visual indicator whose behaviour is calibrated during manufacturing to reflect the known stability profile of the medicine. This design allows pharmacists and pharmacy technicians to quickly identify items requiring attention, facilitating First-Expired, First-Out (FEFO) inventory rotation and reducing reliance on manual date checking.

Method

Two complementary materials-based strategies are proposed to achieve controlled, time-dependent colour transitions in expiry labels. In both cases, the colour evolution is governed by predictable physicochemical processes that can be synchronized with drug stability data. Figure 1 illustrates the overall conceptual framework for integrating colour-changing expiry labels into pharmaceutical packaging and pharmacy workflow. The label is applied during manufacturing, changes colour gradually during storage, and provides intuitive visual cues (green, yellow, red) to support inventory checks and dispensing decisions. Optional integration with digital inventory systems could further enhance monitoring efficiency.

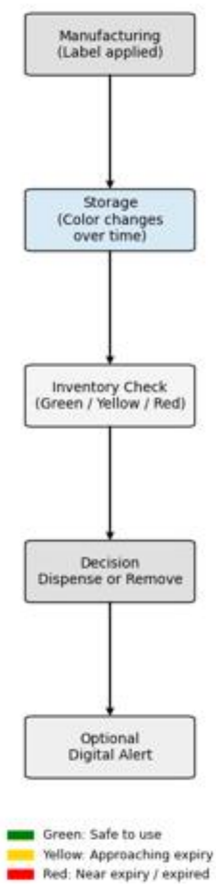

Fig. 1: Conceptual framework showing the integration of a colour-changing expiry label into pharmaceutical packaging and pharmacy workflow.

Structural-coloured polymers

Structural-coloured polymers, such as cholesteric liquid crystal polymers, block copolymer photonic structures, or polymer opal systems, contain periodic nanoscale architectures that interact with visible light to produce colour through physical structure rather than chemical pigments, like photonic crystals (Foelen & Schenning, 2022). Over time, gradual exposure to environmental factors such as heat, humidity, oxidation, or polymer relaxation can induce slow and predictable changes in nanoscale spacing. These structural changes result in a continuous shift in reflected colour, for example from green to yellow and eventually to red. By tailoring polymer composition and degradation kinetics, the rate of colour evolution can be calibrated to match the expected shelf life of a specific pharmaceutical product.

Advantages:

- Passive system requiring no power, electronics, or user input
- Colour evolution can be synchronized with drug degradation timelines
- Structural colour is resistant to dye leaching and accidental tampering

Controlled-release microcapsules

An alternative approach involves microcapsules containing colorimetric dyes embedded within the label matrix. These microcapsules can be engineered to release dye gradually over time via diffusion, dissolution, or environmentally triggered mechanisms such as changes in humidity or temperature (Li & Calle, 2007). Similar microcapsule-based systems have been applied in smart coatings and packaging to achieve time-dependent colour or property changes (Li & Calle, 2007; Kuswandi et al., 2011). The release kinetics of the dye can be mathematically modelled and tuned during label design, so that increasing dye concentration corresponds to a progressive colour transition. As with structural-coloured polymers, the label does not sense drug degradation directly; instead, its release profile is pre-calibrated to align with known drug stability data.

Scientific considerations:

- Released dyes must be chemically inert and isolated from the drug product
- Diffusion or release rates can be quantitatively modelled to match pharmacologically relevant time points
- Microcapsules can be incorporated into adhesives, films, or secondary packaging materials during manufacturing

Figure 2 provides a conceptual illustration of the two mechanisms proposed for enabling time-dependent colour change in expiry labels. The top panel depicts structural-coloured polymer systems, in which nanoscale structural changes gradually alter reflected colour over the product's shelf life. The bottom panel illustrates microcapsule-based labels, in which dyes are released progressively to produce a corresponding colour transition. Together, these mechanisms demonstrate how smart labels could visually indicate remaining potency or shelf life, providing pharmacists and technicians with an intuitive, low-maintenance tool for inventory management. While no physical prototype has yet been developed, these conceptual models provide a foundation for future material design and experimental validation.

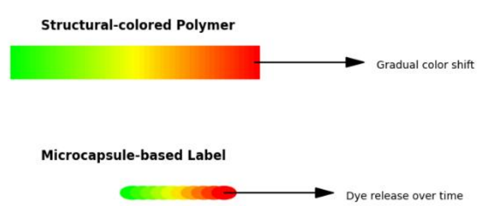

Fig. 2: Conceptual Colour-Changing Label Mechanisms.

Quantitative modelling of label dynamics

A quantitative framework can be used to synchronize label colour evolution with expected drug potency loss, allowing visual identification of medicines approaching critical stability thresholds.

Let:

$C(t)$ = remaining drug concentration (%)

t = time since manufactured

$Color(t)$ = perceived label stage (Green/Yellow/Red)

A first-order degradation model, widely used in chemical and biodegradation studies (Hammershøj, Birch, Redman, & Mayer, 2019), can describe drug potency over time:

$$C(t) = C_0 e^{-kt}$$

where C_0 is the initial drug concentration and k is the degradation rate constant. The colour transition points of the label can then be calibrated to occur before pharmacologically relevant potency thresholds are crossed, for example:

- Green: $C(t) > 90\%$ (safe)
- Yellow: $90\% \geq C(t) \geq 75\%$ (warning)
- Red: $C(t) < 75\%$ (near-expiry/expired)

Figure 3 illustrates a conceptual first-order degradation model of drug potency over time, with color-coded zones representing the proposed label stages: green (safe), yellow (warning), and red (near-expiry or expired). This visualization demonstrates how the label's colour progression can be calibrated to pharmacologically relevant thresholds, providing an intuitive, low-maintenance tool for identifying medicines approaching critical stability limits.

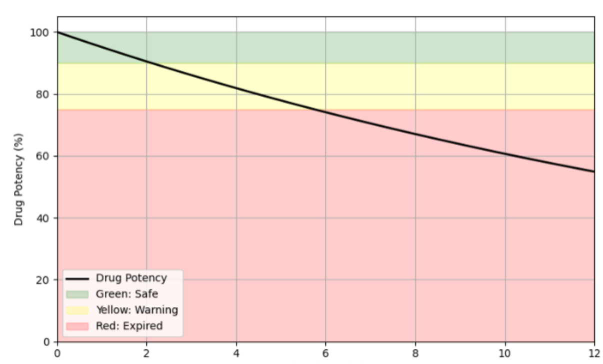

Fig. 3: Conceptual colour-change progression of an expiry label relative to drug potency over time.

While first-order degradation kinetics are routinely used in pharmaceutical stability studies, their application as a design framework for time-based, visually intuitive colour-changing expiry labels is novel. Traditional expiry labelling relies on static printed dates requiring manual interpretation. The proposed approach integrates predictive degradation kinetics with smart material design, offering a quantitative, visual, and low-maintenance strategy for proactive medication safety and inventory management.

Although first-order degradation kinetics provide a useful and widely accepted starting point for conceptual modelling, many pharmaceutical products follow more complex degradation patterns, including multi-phase or temperature-dependent behaviour. In practice, label calibration could rely on ICH stability data obtained from accelerated and long-term studies, with material properties such as polymer relaxation or dye release rates adjusted to match the stability profile of each product. This approach allows the proposed framework to be applied across different drug types without changing its core design concept.

The smart label would be applied during the packaging process and engineered to match the expected shelf life of the medicine. Once activated, it evolves autonomously over time without the need for power, scanning, or user interaction, offering a practical and scalable enhancement to existing pharmaceutical packaging systems.

Results and Discussion: Conceptual Analysis and Roadmaps

This section presents a conceptual evaluation of colour-changing expiry labels, including feasibility, limitations, experimental approaches, regulatory considerations, and future applications.

Feasibility and Potential Benefits

The proposed colour-changing labels have several potential benefits in pharmacy practice. One of the main advantages is improved patient safety. By providing immediate visual cues, these labels can help pharmacists quickly identify expired or sub-potent medications, reducing the risk of dispensing unsafe drugs. The labels can also improve inventory management. For example, in a busy community pharmacy, a technician conducting a routine shelf check could immediately identify near-expiry stock by scanning for yellow or red labels, rather than manually reading printed dates on each package. Products with yellow labels could be prioritized for dispensing, while red-labelled items could be removed before reaching patients. Even in pharmacies using digital inventory systems, the visual cue provided by the label would serve as a rapid, redundancy-based safety layer during high workload periods. Using a first-expired, first-out (FEFO) system, pharmacists can rotate stock more efficiently, minimizing waste and ensuring that medications are used before they expire. In addition, clear visual indicators can enhance patient trust, as patients may feel more confident in the safety and reliability of their medications. Finally, the labels are low maintenance, requiring no power source or electronic components, making them suitable for low-resource settings where technological solutions may be impractical.

Limitations and Challenges

Despite their potential benefits, these smart labels face several limitations and challenges. Material stability is a critical concern, as the polymers and microcapsules used in the labels must withstand fluctuations in temperature, humidity, and light to remain reliable. Cost is another important factor; these labels are more expensive than conventional labels, and studies are needed to determine whether their benefits outweigh the additional expense. Customization is also a challenge because different drugs have different shelf lives and storage requirements. The label design must therefore be adaptable to accommodate these variations while still providing accurate expiration indicators.

Proposed experimental approaches

Several experimental approaches are proposed to validate and optimize the concept of colour-changing labels. In vitro stability testing would involve placing labelled tablets under controlled temperature and humidity conditions. The colour change of the labels would be monitored and correlated with chemical degradation measured by high-performance liquid chromatography (HPLC), a standard method for quantifying drug content over time. Materials testing would assess the photostability, chemical inertness, and environmental tolerance of the polymers and microcapsules used in the labels. Mathematical modelling could simulate dye release or structural degradation to predict the kinetics of colour change under different conditions. Finally, a pilot pharmacy workflow study would evaluate the usability of the labels in real-world settings, measuring time savings and reductions in dispensing errors.

Research Pathway

Further research is needed to fully validate the colour-changing label concept. The first step would involve laboratory development of the colour-changing materials, ensuring they respond accurately to environmental conditions and drug degradation. Once the materials are optimized, pilot testing in pharmacy settings could evaluate practical usability and workflow integration. A cost–benefit analysis and regulatory review would also be essential before considering large-scale implementation, to ensure that the labels provide value without introducing new risks or excessive costs.

Pharmacological and Regulatory Relevance

Colour-changing labels can be designed to align with the therapeutic potency thresholds of critical drug classes, such as antibiotics, antihypertensives, and biologics. Compliance with regulatory standards, including those set by the U.S. Food and Drug Administration (U.S. Food and Drug Administration [FDA], 2003), the European Medicines Agency (European Medicines Agency [EMA], 2024), and ISO packaging guidelines (International Council for Harmonisation [ICH], 2003), would be required for industrial use. In addition to supporting medication safety, these labels could contribute to pre-market drug stability testing and innovation in smart packaging systems. Proper implementation could improve quality assurance across the pharmaceutical supply chain and provide additional safeguards for patients.

Future Applications

There are several potential future applications for colour-changing labels beyond traditional pharmacy settings. They could be used in patients' homes to improve medication adherence and safety, giving clear visual feedback on whether a drug is still potent. In drug donation programs, the labels could help identify usable near-expired stock, reducing waste and improving resource allocation. Finally, these labels could be integrated into digital supply chains, allowing real-time inventory monitoring and providing more accurate tracking of medication shelf life throughout distribution networks.

Conclusion

Colour-changing expiry labels could offer a practical and impactful strategy to improve medication safety and inventory control in pharmacies. Although no prototype exists, the concept builds on established technologies from food and vaccine packaging that can be adapted for pharmaceuticals. Future research should focus on testing suitable materials, evaluating costs, and piloting the system in real pharmacy settings. If successful, this innovation could reduce errors, improve stock rotation, and decrease pharmaceutical waste, particularly in resource-limited environments.

Authors contributions

Conceptualization, methodology, investigation, data curation, writing of the original draft, writing review and editing, supervision, and project administration were carried out by Pinar. The author has read and approved the final version of the manuscript.

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Conflict of interest

The author declares no conflicts of interest.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this manuscript, AI assisted technologies such as ChatGPT were used to improve language and readability. The author has reviewed and edited the content and takes full responsibility for the final manuscript.

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